K131905
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510(k) Summary

JUL 1 8 2013

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: ___06/18/2013___

1. Submitter:

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Contact:	Heecheon Chae, CEO

2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
1515 E. Katella Ave. Unit 2115,
Anaheim, CA 92805
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Email: juhee.c@lkconsultinggroup.com

3. Device:

Proprietary Name:	SOLID GEL PAD
Common Name:	Ultra Sound Gel Pad
Classification Name:	Ultrosonic pulsed echo imaging system accessory
Classification:	Class II, 21 CFR 892.1570
Classification Product Code:	MUI

4. Predicate Device:

Sheathes Ultrasound Gel (K112827) by Sheathing Technologies, Inc
Thixo-Gel Ultrasound Spray (K121311) by Christina Bernstein BB Medical Surgical, Inc.

5. Device Description:

The SOLID GEL PAD is ultrasound gel of the solid-state, generally used for ultrasound scanning for imaging diagnosis or ultrasound stimulator for treatment. The gel pad will be

sold for single patient/procedure, disposable use. The SOLID GEL PAD is 9cm x 9cm aqueous, flexible, disposable ultrasound standoff for use in difficult to visualize and near field areas, or when gels alone won't do. Disposability eliminates the risk of cross contamination in diagnostic and therapeutic ultrasound procedures. It requires only gentle, even pressure.
The SOLID GEL PAD is especially very useful for using ultrasound over areas that are bony such as fingers, hands, wrists, elbows, and ankles. It also allows visualization of superficial structures.

6. Intended Use:

Non-sterile ultrasound couplant for use with medical diagnostic ultrasound. It is intended to be used during non-invasive medical diagnostic ultrasound procedures to couple sound waves between a patient and the medical imaging electronics. The gel is intended for use in all diagnostic ultrasound procedures which require ultrasound coupling gel or liquid or fluid.

7. Performance Data(Non-Clinical):

The following properties were tested based on the referenced standards. All the test results supported that the subject device is substantially equivalent to the predicate device in safety and effectiveness.

- ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro Cytotoxicity (Biocompatibility)
- ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (Biocompatibility)
- ISO 12185 : 2003 Crude petroleum and petroleum products-Determination of density-Oscillating U-Tube method
- KS M 2014 : 2004 Testing methods for kinematic viscosity and calculating method for viscosity index of crude oil and petroleum products

8. Substantial Equivalence

The SOLID GEL PAD is substantially equivalent to the Sheathes Ultrasound Gel (K112827) and Thixo-Gel Ultrasound Spray (K121311). They all are water based gel, but some compositions are different among the devices. The subject device is a gel pad type, whereas, the predicate devices are gel(K112827) and spray(K121311) type respectively. Despite these differences, we believe that the performance and biocompatibility testing results proves that the subject device is substantially equivalent to the predicate devices in safety and effectiveness.

9. Conclusion:

Based on the testing results, BLUEMTECH concludes that the SOLID GEL PAD is safe and effective also, substantially equivalent to predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 18, 2013

BLUEMTECH
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1515 E. Katella Avenue, Unit 2115
ANAHEIM CA 92805

Re: K131905
Trade/Device Name: SOLID GEL PAD
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: MUI
Dated: June 17, 2013
Received: June 26, 2013

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131905

Device Name: SOLID GEL PAD

Indications for Use:

Non-sterile ultrasound couplant for use with medical diagnostic ultrasound. It is intended to be used during non-invasive medical diagnostic ultrasound procedures to couple sound waves between a patient and the medical imaging electronics. The gel is intended for use in all diagnostic ultrasound procedures which require ultrasound coupling gel or liquid or fluid.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K131905